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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,556	06/14/2001	J. Neil Simonsen	9000-0054	6837

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[REDACTED] EXAMINER

NAVARRO, ALBERT MARK

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/881,556	Applicant(s) Simonsen
Examiner Mark Navarro	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 2, 5, and 9-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3, 4, and 6-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 & 8
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II, claims 1, 3-4, and 6-8 in Paper No. 9, received October 15, 2002 is acknowledged. The traversal is on the ground(s) that the Office should not be imposing restriction between AG1 and AG2, or even a species election between the two antigens. Applicant's point to MPEP 803.02 which sets forth that if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. This is not found persuasive because as set forth in MPEP 803.04 biological molecules with different sequences are unrelated to one another, and are normally constituted independent and distinct inventions. It is the Examiner's position that multiple searches for independent and distinct inventions is burdensome. A reference which anticipates one protein would not necessarily anticipate or render obvious a different protein. Finally, Applicant's assert that the members of the Markush group must be examined even though they are independent and distinct. However MPEP 803.02 sets forth that for Markush claims to be examined in their entirety they must display unity of invention by sharing both a common utility and share a substantial structural feature disclosed as being essential to that utility. The first ten N

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terminus amino acids of AG1 identified in Figure 1 are “ARELPSDRSN” while the first ten N terminus amino acids of AG2 identified in Figure 2 are “HEIFFFLLPI.” As can be clearly seen not even a single amino acid is identical. Consequently, Applicant’s “substantial structural feature” is lacking and unity of invention is not afforded.

Consequently, claims 1-31 are pending in the instant application, of which claims 2, 5, and 9-31 are withdrawn as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because Applicant’s specification (Page 5) sets forth that Figures 1A-1B show the amino acid sequence (SEQ ID NO: 2) of C. parvum AG1. Applicant’s specification further sets forth that Figures 2A-2B show the amino acid sequence (SEQ ID NO: 4) of C. parvum AG2. However, Applicant’s paper copy and electronic copy of the sequence listing both recite nucleic acid sequences for SEQ ID NO: 1-4. Correction is required. See MPEP § 608.01(b).

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Claim Rejections - 35 USC § 112

3. Claims 1, 3-4, and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1, 3-4 and 6-8 recite an isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide comprising a *C. parvum* antigenic polypeptide 2 (AG2), or a fragment of said nucleic acid molecule comprising at least 15 nucleotides, and wherein the nucleotide sequence has at least about 80% identity to the nucleotide sequence shown at nucleotide positions 8-394, inclusive, of Figure 1A (SEQ ID NO: 1).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 3 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 3 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed

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genus. It is further noted that SEQ ID NO: 3 does not appear to be a full length protein, given that the classical start codon, methionine, is absent.. Given that the function of the non-full length protein is not set forth, the written description of the instant application is supportive of only an antigenic peptide consisting of SEQ ID NO: 3 (note, given Applicant's confusion in labeling the protein as set forth above, the protein will also be identified as SEQ ID NO: 3), since additional amino acids on the N-terminus or C-terminus will have a profound impact on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are vague and indefinite in the recitation of “at least about 80%” and “at least about 15 nucleotides.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. “At least” one thousand degrees in claim means minimum temperature of one thousand degrees “About” in claim allows some tolerance. National Research Development Corp v. Great Lakes Carbon Corp. (DC Del) 188 USPQ 327. Consequently, the term at least about confers two separate contradictory limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1, 4, and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Perryman *et al.*

The claims are directed to an isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide comprising a *C. parvum* antigenic polypeptide 2 (AG2), or a fragment of said nucleic acid molecule comprising at least 15 nucleotides.

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Perryman *et al* (U.S. Patent Number 6,323,020) disclose of an isolated nucleic acid molecule comprising a DNA coding sequence for an immunogenic *C. parvum* polypeptide with a molecular weight of 23 kDa. Perryman *et al* further disclose of vectors, host cells, and methods of expressing the polypeptide. (See claims and column 5).

In view that Applicant's specification sets forth that *C. parvum* antigenic polypeptide 2 is determined to be 21.8 kDa, and that the nucleic acid disclosed by Perryman *et al* encodes a *C. parvum* polypeptide with a molecular weight of 23 kDa, the disclosure of Perryman *et al* is deemed to anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

December 26, 2002